


FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DKT NO. B185 1180.1		SERIAL NO. 10/670,896	
		INFORMATION DISCLOSURE STATEMENT BY APPLICANT					
		APPLICANT Hotta, <i>et al.</i>				FILING DATE 09/25/03	
				GROUP 3762			
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CL.	SUBCL.	FILING DATE IF APPROP.
ADK	P1	US 2002/0192794 A1	12/19/02	Dadd, <i>et al.</i>	435	217	
	P2	US 2002/0009707 A1	01/24/02	Nur, <i>et al.</i>	435	2	
	P3	6,096,872 A	08/01/00	Van Holten, <i>et al.</i>	530	390.1	
	P4	5,886,154	03/23/99	Lebing, <i>et al.</i>	530	390.1	
ADK	P5	2,390,074	12/04/45	Cohn, <i>et al.</i>	260	122	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NO.	DATE	COUNTRY	CL.	SUBCL.	TRANSLATION
ADK	F1	EP 1 206 961 A1	05/22/02	EP			
ADK	F2	WO 01/36611 A1	05/25/01	WO			
ADK	F3	WO 98/37086	08/27/98	WO			
OTHER DOCUMENTS (Incl. Author, Title, Date, Pertinent pages, etc.)							
ADK	D1	Abe, H., <i>et al.</i> , "Removal of Parvovirus B19 from Hemoglobin Solution by Nanofiltration," <i>Art. Cells, Blood Subs., and Immob. Biotech.</i> , 28(5): 375-383 (2000).					
	D2	Aranha, H., "Viral Clearance Strategies for Biopharmaceutical Safety Part 2: Filtration for Viral Clearance," Reprinted from <i>Biopharm.</i> , 8 pages (2001).					
	D3	Burnouf-Radosevich, M., <i>et al.</i> , "Nanofiltration, a New Specific Virus Elimination Method Applied to High-Purity Factor IX and Factor XI Concentrates," <i>Vox. Sang.</i> , 67(1): 132-138 (1994).					
	D4	Burnouf-Radosevich, M., "Viral Safety of Intravenous Immunglobulins G for Therapeutic Use," <i>Transfus. Clin. Biol.</i> , 2(3): 167-179 (1995).					
	D5	Carter, J., and H. Lutz, "An overview of viral filtration in biopharmaceutical manufacturing," <i>European Journal of Parenteral Sciences</i> , 7(3): 72-78 (2002).					
	D6	Hotta, J., <i>et al.</i> , "Significant Parvovirus Removal and Product Recovery from an IgG-containing Solution using Planova Filters," PDA/FDA Viral Clearance Forum, 1 page (October 2001).					
	D7	Ide, S., "Development of New Planova® Membrane – the Planova® 20N Filter," Planova® Workshop Tokyo, Japan, pp. 135-145 (November 1, 2000).					
	D8	Korneyeva, M., "Factors Influencing Virus Removal and Product Yield During Nanofiltration of Highly Purified Plasma-Derived Protein with Thrombolytic Activity," <u>Slides from Oral Presentation</u> , 29 th World Congress of the International Society of Hematology, Seoul, Korea, pp. 1-17 (August 24-28, 2002).					
	D9	Li, H., <i>et al.</i> , "Low pH of Feed Solutions Significantly Increases Procine Parvovirus Aggregate Formation," <u>Slides from Oral Presentation</u> , PDA/FDA Viral Clearance Forum, Washington, DC, pp. 1-18 (October 1-3, 2001).					
ADK	D10	McNaull, S., <i>et al.</i> , "Parvovirus Removal from an IgG-containing Solution at Extended Challenge Volume Using an Ultrafiltration Membrane in Normal-Flow Configuration," <u>Slides from Oral Presentation</u> , PDA/FDA Viral Clearance Forum, Washington, DC, pp. 1-12 (October 1-3, 2001).					
EXAMINER				DATE CONSIDERED			
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use several sheets if necessary)</i>				APPLICANT Hotta, <i>et al.</i>	
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OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, etc.)</i>					
ADK	D11	O'Grady, J., <i>et al.</i> , "Virus Removal Studies Using Nanofiltration Membranes," Viral Safety and Evaluation of Viral Clearance from Biopharmaceutical Products, <i>Dev. Biol. Stand.</i> , 88: 319-326 (1996).			
	D12	Omar, A., and C. Kempf, "Removal of Neutralized Model Parvoviruses and Enteroviruses in Human IgG Solutions by Nanofiltration, <i>Transfusion</i> , 42: 1005-1010 (2002).			
	D13	Troccoli, N.M., <i>et al.</i> , "Removal of Viruses from Human Intravenous Immune Globulin by 35 nm Nanofiltration," <i>Biologicals</i> , 26: 321-329 (1998).			
	D14	Planova® Filters, Planova® Filters for Virus Removal, Asahi Kasei Corporation, Planova® Division, 4 pages, www.asahi-kasei.co.jp/planova/product/filters.html (date of public availability unknown).			
	D15	Section 3.1. <u>Virus validation studies for Parvovirus B19</u> , Plasma Protein Therapeutics Association Europe, pp. 5-9 (February 14, 2000).			
	D16	Planova® Workshop 2002, Biotherapeutic Production, Safety, and Validation with Planova® Filtration Products, Bethesda, Maryland, USA, Asahi Kasei Corporation, entire publication, (October 10, 2002).			
	D17	Planova® Workshop 2001, Virus removal filtration: applications, advances, and analyses, Montecatini Terme, Italy, Asahi Kasei Corporation, entire publication, (September 24 - 25, 2001).			
	D18	Planova® Workshop Japan, A forum for exchanging information on the latest developments in virus removal filtration, Tokyo, Japan, Asahi Kasei Corporation, entire publication, (November 1, 2000).			
	D19	Planova® Workshop USA '99, A forum for exchanging information on the latest developments in virus removal technology, Washington, DC, USA, Asahi Chemical Industry Co., Ltd., entire publication, (November 29, 1999).			
ADK	D20	Planova™ Workshop, To meet and exchange information on the latest developments in virus removal technology, Oslo, Norway, Asahi Chemical Industry Co., Ltd., entire publication, (June 27, 1998).			
EXAMINER /Andrew D. Kosar/				DATE CONSIDERED 05/26/2006	
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